

EXHIBIT 5-d

1 But my understanding, and we believe we have cited
2 in our papers, the A numbers, the administrative record
3 numbers of where the models are. I can point the Court to
4 that page if you would like me to.

5 THE COURT: That's all right.

6 MS. WETZLER: Turning then to some of the other
7 arguments regarding the completeness of this record.
8 Basically this breaks down into four categories. And I won't,
9 I am not going to run through 1 through 5 of the type of
10 plaintiff's or GSK's requests because we have done that in our
11 papers and we stand behind that.

12 But there are generally four categories, four
13 reasons why they haven't shown the record to be incomplete.
14 Many of the materials that they cite are actually in the
15 record. And I know Your Honor said you had an opportunity to
16 look at the papers and we have explained, we have cited to the
17 Federal Register notice many times, we have cited to the A
18 numbers in the record. They are there. The vast amount is
19 deliberative.

20 We have irrelevant materials because there are
21 questions of law. Plaintiffs are calling for discovery on
22 issues that simply don't need additional supplementation.

23 And as Your Honor has repeatedly come back to, the
24 vast majority of what plaintiffs are asking for are their
25 arguments for remand. They are simply arguments as to why the

1 agency has acted in an arbitrary and capricious manner. They
2 are not arguments for discovery. They do not rebut the
3 presumption of regularity that exists.

4 On the bad faith issue, again, GSK has said that--

5 THE COURT: Ms. Wetzler, I have to tell you that the
6 revelation, if that's the right word, that the attorneys
7 involved were not even consulted about materials that might be
8 in their possession, leads me to wonder about the presumption
9 of regularity.

10 MS. WETZLER: Your Honor, if I could emphasize again
11 how this was done. The individuals who were responsible for
12 pulling together the administrative record had been involved
13 in this rule making for two years. They knew what materials
14 were indirectly or directly considered that were
15 nondeliberative in nature. They knew where to look for them.
16 They pulled them. They did not need to go to 20 to 30 other
17 people who were attorneys and whose role was simply to provide
18 advice. The role of those attorneys was to engage in
19 deliberations. And that is why it wasn't necessary.

20 And I see my client writing something, if I may just
21 take a moment and see.

22 THE COURT: Certainly.

23 MS. WETZLER: Your Honor, Ms. McDowell has corrected
24 something that I said. Apparently they, there was
25 consultation with these attorneys for any materials that they

1 had that would be considered within the record. What was not
2 asked for was for them to physically give the deliberative
3 materials.

4 So, they were in fact, I am now being corrected,
5 they were in fact consulted, but they simply did not
6 previously give over the deliberative materials.

7 THE COURT: All right.

8 MS. WETZLER: So, I would like to correct the record
9 on that score.

10 THE COURT: Thank you.

11 MS. WETZLER: I think, Your Honor, we will stand on
12 our papers except to point out, again, that what the
13 plaintiffs are asking for is extensive discovery. It is a
14 fishing expedition.

15 Tafas is asking for depositions of high level agency
16 officials, which is clearly impermissible under the Morgan
17 line of cases absent some showing of bad faith, which they
18 clearly have not made. Bad faith is a serious charge to level
19 against an agency.

20 THE COURT: I heard you.

21 MS. WETZLER: And there is absolutely no basis for
22 that charge in this case. GSK's production requests are
23 similarly extensive, as Your Honor used that word. If one
24 looks at the production requests in particular, they are broad
25 ranging. They cover the universe of these rules.

1 These are not narrowly targeted, they are not even
2 congruous with their specific defects they have pointed out.
3 And in fact, those defects do not exist at all.

4 Thank you, Your Honor.

5 THE COURT: Thank you. Mr. Nealon, briefly.

6 MR. NEALON: Just a couple of quick points. One, I
7 think in terms of what the remedy here is. Again, I think
8 there were a couple of appropriate remedies. Certainly remand
9 is one option.

10 We are not hearing from the PTO side, we don't need
11 to do depositions, we don't need to do document discovery, we
12 think that there are some problems, we would like to
13 supplement and complete the record through a remand. We are
14 not hearing that.

15 What we are hearing is, we gave you everything we
16 think that you are entitled to as part of the administrative
17 record, you know, based on the criteria that we used to come
18 up with that record.

19 And again, just kind of echoing the points that Mr.
20 Desmarais made, we just think that that process is very
21 faulty. We think that the output, we look and it and we say,
22 well, where is a lot of the stuff that we would expect to
23 find, particularly pre-January 2006 when this was proposed?

24 400 pages is not a lot. And I think of the 400
25 pages, quite a bit of it is public reports, some of them going

1 back to the 1990s.

2 THE COURT: I understand.

3 MR. NEALON: We probably have more than 400 pages in
4 briefing and exhibits, you know, for this particular motion.

5 So, I think the question is, should this be remanded
6 to the agency, which probably puts us much further back
7 getting to the root of what the record is. And if there is
8 disputes, it probably percolates back up to be dealt with this
9 Court again.

10 You know, or do we use the other procedure that is
11 viable and as set forth in the Fourth Circuit cases, you know,
12 basically saying, you can use discovery to do this purpose.

13 And again, I think to the extent that GSK's attorney
14 was saying that their discovery is narrow and targeted and
15 ours is, you know, maybe implying broad and sweeping, I don't
16 think that's true.

17 I mean, what we are both seeking here, the
18 plaintiffs, is the true administrative record. And we want to
19 go forward confident that we have everything that was
20 considered directly or indirectly by the decision makers
21 whomever they were, which we don't know based on this record.

22 And that if there are assertions of privilege, that
23 they are well founded and supportable so that factual
24 information and models and analysis and other things that we
25 might be entitled to are set forth in the record so that we

1 can challenge them.

2 Again, you know, I think what is bad faith? Bad
3 faith is when you say one thing in one forum and something
4 different in another forum.

5 Here there are statements being made to the OMB to
6 one effect, and then there are contrary statements that we
7 have set forth in our papers to another effect.

8 We think that the agenda here was, and we are seeing
9 this in documents we are finding on the Internet, statements
10 by PTO officials, to reduce the workload, to stop the inflow
11 of new work into the Patent Office in terms of having to deal
12 with multiple claims and continuations, and that the safety
13 valves that the PTO says in their stated reasons make this
14 about process and not about substance, were not believed to be
15 safety valves by the PTO.

16 Now, whether document discovery, whether we are able
17 to get documents that are going to show that, I don't know.
18 And you could draw an inference of bad faith perhaps from
19 those documents. I think that there are documents out there
20 that may not be covered by the deliberative process privilege
21 that would show that.

22 But what the PTO is trying to say is, look, you are
23 entitled to prove bad faith, you just have to do it based on
24 our stated reasons.

25 Well, no agency is going to put their bad faith, and

1 if they have some contrary or ulterior motive for doing these
2 rules, on the face of the records. I mean, they anticipated
3 litigation on these from day one.

4 So, the question is, first and foremost, we need to
5 have a proper record. And then I think the question comes up
6 about depositions. I mean, the more that I am hearing here
7 about the process that the PTO used, you know, it is kind of
8 making me rethink a little bit about what the deposition order
9 if they are permitted should be.

10 I mean, maybe the first order of business is some
11 dialogue or conversation with those who actually put this
12 record together so we can get to the heart of exactly how this
13 was done, whether an appropriate privilege review was done.

14 We would certainly like to see the PTO, you know, do
15 that in the first instance and come forward and say, look,
16 we've focused on your concerns, here is additional
17 information, here is your privilege log, we are prepared to
18 stand behind it, we don't think you should be permitted
19 discovery, but if Judge Jones permits you discovery, it is
20 going to be a waste of your time because you are not going to
21 find anything. You have gotten what you are entitled to.

22 But as we sit here today, we don't think we have
23 what we are entitled to. And to prove our bad faith claims,
24 we need to be given a little bit of latitude to do that.

25 We think we have shown a sufficient indicia of

1 contrary statements that were made in different forums in our
2 papers. You know, that perhaps-- Well, doesn't perhaps. I
3 mean, it calls for further investigation.

4 And if we had a complete record, if someone could
5 stand up and say, you know, to a certainty, this is
6 everything, you are not going to find bad faith, you know,
7 maybe we approach it differently.

8 But there are so many holes at this point and so
9 many uncertainties about whether this is a proper record, it
10 is feeding that concern we have about bad faith and whether
11 something is being hidden here.

12 So, to some extent, I mean, we are the camel's nose
13 under the tent. We want to find out what really happened
14 here. And what we are faced with are these kind of vague,
15 sweeping assertions of privilege, very sweeping assertions as
16 to timeframes that are off limits or not appropriate. That's
17 not based on anything.

18 There are 20 or 30 attorneys, you know, who
19 apparently have information relating to this and were involved
20 in the rule making. I mine, that's a revelation to me. But
21 it goes back to a point I was making to Your Honor this
22 morning, we think that the Solicitor's Office anticipated
23 litigation on this from day one. Mr. Whealan was a huge
24 advocate going back several years when he contributed to law
25 review articles favoring curbing continuations of this policy,

1 and a lot of the rule making may have been done out of the
2 legal, you know, department of the office. But it doesn't
3 insulate the whole rule making process based on privilege.

4 You know, so that's our position. It sounds to me,
5 it is really a question of how we get this administrative
6 record.

7 From our point of view, the most direct way is for
8 the PTO to come forward with a proper privilege log so we can
9 look at it. If there are things that are being withheld that
10 shouldn't be withheld based on a subsequent document review of
11 these materials that no one has apparently looked at, they
12 should supplement the record with those. And then perhaps we
13 revisit the question of whether there is material that would
14 further support a showing of bad faith and we could get a
15 better focus on deposition. But that piece of it has to be
16 resolved, and it is just a question of how we get there.

17 Remand is a possibility, but I am not sure it
18 functionally changes where we go with it. You know, the issue
19 is at the end of the day, the PTO needs to give us the true
20 record. And that's really what this is all about.

21 Thank you.

22 THE COURT: Thank you.

23 MR. DESMARAIS: Your Honor, if I might just briefly
24 respond.

25 THE COURT: Yes, sir.

1 MR. DESMARAIS: I think that Your Honor picked up on
2 a very important point that I was making in my opening
3 comments and I will just reiterate now.

4 It's clear that there shouldn't be a presumption of
5 regularity in this case because it has been rebutted.
6 Certainly the PTO started with that, but for the, for all the
7 reasons I said in my opening comments, which I won't repeat
8 now, there are clearly documents missing from the record that
9 the Patent Office, if you look at their responsive brief, do
10 not argue don't exist. They argue that they are not in the
11 record. They agree with that.

12 And then when we look at how the documents were
13 collected, how the administrative record was put together,
14 clearly it wasn't done properly.

15 If there were 20 to 30 employees in the Patent
16 Office whose files were not reviewed to create the record,
17 clearly there are things in there that should be in the record
18 that aren't.

19 And when you look at what our discovery is targeted
20 to, it is very targeted discovery. Tab B to our brief is just
21 three interrogatories, and they are very targeted.
22 Interrogatory Number 1: Describe any models used to justify
23 the predictions about how the proposed and the final rules
24 would reduce the PTO's workload, with an explanation of the
25 model and how it functions in the assumptions.